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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,568	07/16/2001	Johanne Tremblay	004780.00001	3854

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,568	TREMBLAY ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,6-52 and 59-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2,6-10,14-18 and 22-46* is/are allowed.

6)☒ Claim(s) *11-13,19-21,47-52 and 59-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2004 has been entered.

Status of Application/Amendment/Claims

2. Applicant's response filed July 29, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed March 9, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Listing

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The

disclosure contains sequences which fall under the purview of 37 CFR 1.821 through 1.825 as requiring SEQ ID NOS:, but which are not so identified. For example, the figures contain sequences in excess of 10 nucleotides long, but are not identified by a SEQ ID NO:. Applicants should be aware that this sequence may not be the only instance necessitating this notice. Applicants should carefully review the application for any further examples of failures to identify any sequences by SEQ ID NO:, and to otherwise verify that the application is in compliance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11 and by dependency claims 12, 13, 19-21, 47-52, and 59-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The invention of the above claims is drawn to a purified nucleic acid of at least 12 nucleotides in length, wherein the nucleic acid molecule comprises a coding portion of SEQ ID NO:1 between nucleotides 295 and 966, a coding portion of SEQ ID NO:3 between nucleotides 132 and 803, a sequence complementary to the coding portion of SEQ ID NO:1, or a sequence complementary to the coding portion of SEQ ID NO:3, wherein said purified nucleic acid is a Hypertension-Related Calcium-Regulating molecule.

It is not clear what "Hypertension-Related Calcium-Regulating molecule" refers to. The specification does not refer to any molecule that regulates hypertension-related calcium as

directly stated. Furthermore, it is not clear how hypertension-related calcium differs from other types of calcium. If the claim is intended to recite a molecule which regulates the expression of Hypertension-related Calcium-Regulated Gene (i.e. a HCaRG directed antisense molecule), then the claim should be amended to reflect this. However, this interpretation is contra-indicated by dependent claims 12 and 13, which state that the subject oligo is also an amplification primer or a hybridization probe, because the specification has not disclosed a molecule which functions as both a HCaRG regulating antisense molecule and an amplification primer or probe. Claim 11 is thus considered vague and indefinite, because the literal interpretation cannot be determined from reading the specification, and because the intended meaning of the claim cannot be easily inferred from the context of the remaining claims.

5. Claims 11 and by dependency claims 12, 13, 19-21, 47-52, and 59-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is drawn to a purified nucleic acid of at least 12 nucleotides in length, that hybridizes to a nucleic acid molecule, wherein the nucleic acid molecule comprises a coding portion of SEQ ID NO:1 between nucleotides 295 and 966, a coding portion of SEQ ID NO:3 between nucleotides 132 and 803, a sequence complementary to the coding portion of SEQ ID NO:1, or a sequence complementary to the coding portion of SEQ ID NO:3, wherein said purified nucleic acid is a Hypertension-Related Calcium-Regulating molecule.

It is not clear which nucleic acid is being referred to by the statement "wherein the nucleic acid molecule comprises..." of claim 11, since there are two previously referred to nucleic acids. Although only one of the antecedent nucleic acids is referred to as a nucleic acid

"molecule", both nucleic acids are nevertheless considered to be molecules, and the claim is therefore considered indefinite. Furthermore, because all dependent claims included in this rejection refer back to "the nucleic acid as defined in claim 11", it is unclear whether the nucleic acid being referred to in the dependent claims is directed to the target or the complement.

In the art rejection that follows, it is assumed that "the nucleic acid molecule" in question refers to the nucleic acid molecules of SEQ ID NOS: 1 or 3, since that is what is most directly suggested by the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 11, and by dependency claims 12, 13, 19-21, 47-52, and 59-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claim 11 is drawn to a purified nucleic acid of at least 12 nucleotides in length that hybridizes to a nucleic acid molecule, wherein the nucleic acid molecule comprises a coding portion of SEQ ID NO:1 between nucleotides 295 and 966, a coding portion of SEQ ID NO:3 between nucleotides 132 and 803, a sequence complementary to the coding portion of SEQ ID NO:1, or a sequence complementary to the coding portion of SEQ ID NO:3, wherein said purified nucleic acid is a Hypertension-Related Calcium-Regulating molecule.

The amendment of July 29, 2004 is considered to refer to two general instances of new matter. They are 1) the amendment to add language to claim 11defining specific target regions of SEQ ID NOS: 1 and 3 (i.e. a coding portion of SEQ ID NO:1 between nucleotides 295 and 966, and a coding portion of SEQ ID NO:3 between nucleotides 132 and 803), and 2) the addition of language specifying particular lengths of oligonucleotides found in claims 59-74.

Regarding the first instance, a review of the specification has turned up no apparent instance in which the specific regions of SEQ ID NO:1 between nucleotides 295 and 966, nor the coding portion of SEQ ID NO:3 between nucleotides 132 and 803 were ever contemplated as regions to design oligonucleotides against. As per M.P.E.P. § 706.03(o):

> "New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter."

In this case, because the added language directed to a narrow region of SEQ ID NOS: 1 and 3 were apparently not in the specification as originally filed, and because the introduction of such language is considered analogous to introducing specific percentages or compounds as discussed in the M.P.E.P. passage cited above, the addition of this language drawn to narrower regions of SEQ ID NOS: 1 and 3 is considered new matter. Should applicants disagree, applicants are invited to point out with particularity by page and line number where support for such language exists in the specification as originally filed.

In regards to the second instance of new matter, applicants have added limitations in claims 59-74 which specify that claimed oligos comprise at least 15, 18, 30, 33, 36, and 39 contiguous nucleotides. In support, applicants have pointed to figure 4, which shows an

alignment of rat and human HCaRG. Applicants allege that support is provided because "[r]egions of homology are indicated by shaded boxes that contain various numbers of contiguous amino acids (e.g., 5, 6, 10, 11, 12, 13, 16, and 18). A disclosure of 5 contiguous amino acids inherently discloses 15 contiguous nucleotides because each amino acid is encoded by a codon that contains three nucleotides. Similarly, a disclosure of 6, 10, 11, 12, 13, 16, and 18 contiguous amino acids inherently discloses a nucleic acid of 18, 30, 33, 36, 29, 48, and 54 contiguous nucleotides, respectively." (page 8 of applicants response, dated July 29, 2004).

Thus, applicants are relying upon small regions of homology between amino acid sequences to claim oligonucleotide fragments. This is simply not considered to be adequate support. In order for this to be considered support, one of skill in the art would need first to look at small regions of homology between amino acid sequences from different species and then view them out of that context as amino acid fragments, and then further envision their pre-translated form as oligonucleotides. A review of the specification has revealed no teachings that would lead one of skill to make these two independent connections to arrive at applicants instantly claimed invention. The support applicants have provided is simply not considered to be in the context of the invention as now claimed, and is thus considered new matter.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under these sections made in this Office action:

> A person shall be entitled to a patent unless –
>
> 102(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

> has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> 103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 11-13, 19-21, 59, and 60 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Manos *et al.* (U. S. Patent Number 5,447,839).

Claim 11 is drawn to a purified nucleic acid of at least 12 nucleotides in length, that hybridizes to a nucleic acid molecule, wherein the nucleic acid molecule comprises a coding portion of SEQ ID NO:1 between nucleotides 295 and 966, a coding portion of SEQ ID NO:3 between nucleotides 132 and 803, a sequence complementary to the coding portion of SEQ ID NO:1, or a sequence complementary to the coding portion of SEQ ID NO:3, wherein said purified nucleic acid is a Hypertension-Related Calcium-Regulating molecule. Claims 12 and 13 comprise the same molecule which is an amplification primer, or a probe. Claims 19-21 comprise the above molecules in composition with a carrier. Claims 59 and 60 comprise the above nucleic acids that comprise 15 or 18 contiguous nucleic acids.

SEQ ID NO: 6 possesses 84% sequence identity with residues 448 through 466 of SEQ ID NO: 3 the instant application, and is thus presumed to specifically hybridize with the complement of the coding portion of SEQ ID NO: 3. Although this reference does not specifically teach the function of regulating Hypertension-Related Calcium as claimed in the present application, this sequence of the prior art meets all the structural limitations as set forth in the instant claims. Furthermore, because the compound is taught in composition with a carrier, and is at least 15 or 18 nucleotides long, and because the sequence is substantially identical to applicant's claimed compounds, in the absence of evidence to the contrary the compound of the prior art is thus considered to anticipate and/or render obvious the compound of the instant invention.

Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection**. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15

USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the compounds of the instant claims are considered anticipated and/or obvious as outlined above.

Allowable Subject Matter

8. Claims 2, 6-10, 14-18 and 22-46 are allowed for reasons of record.

Conclusion

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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JDS

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